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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,368	BERGMANN ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV (claims 1-5, 7 with respect to pro-ANF) in the reply filed on 10/10/2006 is acknowledged.

The traversal is on the ground(s) that the restriction is improper since the examiner has not shown that examination of Groups I-X would be a serious burden on the Examiner. Applicants also argue that claim 2 contains a Markush group of vasoactive peptide prohormones and have a common structural element, that is, that they possess an amino terminal site that is cleavable by a dipeptidyl-aminopeptidase. However, this argument is not persuasive and contrary to Applicants arguments, because pro-endothelin-1, pro-brain-natriuretic peptide, pro-atrial-natriuretic peptide and pro-adrenomedullin are disparate hormones and differ structurally and functionally. Furthermore, a search for one of these pro-hormone peptides in the claimed method would not necessarily reveal art for any of the other pro-hormone peptides, eg. a search of the literature for an association of pro-END with sepsis would not necessarily reveal art for an association of pro-ADM with sepsis. The novelty of the inventions in the different Groups is in the products being detected in the instant methods and not the methods themselves. The only feature in common in the instant inventions is "a method for the differential-diagnostic early detection", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as IL-1. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products to be detected in the different Groups are

physically, chemically and biologically distinct from each other, and if patentable would support separate patents.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5 and 7 will only be examined with respect to a pro-ANP or pro-ANF. Claim 6 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 1-5, 7 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for the differential-diagnostic early detection and detection, for the assessment of the severity, and for the assessment of the success of a therapeutic treatment of sepsis and severe infections, in particular sepsis-like systemic infection, characterized in that the content of at least one peptide prohormone other than

procalcitonin and/or of a partial peptide derived therefrom, which is not the mature hormone obtainable from said peptide prohormone, is determined in a sample of a biological fluid of a patient, and the presence of a sepsis or sepsis-like systemic infection, its severity and/or the success of a therapeutic treatment are determined from the detected presence and/or amount of the determined peptide prohormone.

The claims require assaying a "biological fluid" but does not recite how and with what the "biological fluid" is assayed. The claims, do not require that the "biological fluid" recited in the claim 1, and the peptide prohormone to be assayed be a compound possessing any particular conserved structure, or other distinguishing feature.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a recitation of determining the presence of a peptide prohormone content in biological fluid. The specification does not identify any particular structure, nor does it provide a disclosure of structure/function correlation of the peptide prohormone. The distinguishing characteristics of the claimed genus of peptide prohormone are not described. Accordingly, the specification does not provide adequate written description of the claimed genus of "peptide prohormone".

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in

the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since invention consists of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since specification did not indicate that

compounds are available in public depository, the claimed treatment method cannot be practiced without compound. Thus the inventors cannot be said to have "possessed" claimed invention without knowing of a compound or method certain to produce compound. Thus, said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compound defined only by their desired properties. Therefore, the full breadth of the claims failed to meet the written description provision of 35 U.S.C. §112, first paragraph.

In the instant case, for example, Applicants have failed to describe which peptide prohormone is encompassed by the claims, what is the biological sample to be used in the instant method, and a description of the claimed method, and the reason or rationale for the diagnosis that the subject has sepsis.

Further, the instant specification does not provide an adequate description of the genus of reagents to detect the prohormone encompassed by these claims. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. The instant specification does not provide a description of a method for detecting all neoplasia using all affinity reagents to filamin A. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is

the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification does not provide an adequate description of the genus of methods encompassed by these claims. *Vas-cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the written description' inquiry, whatever is *now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of prohormones, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only a method of diagnosing whether a subject has sepsis by immunoassaying pro-ANF from said subject for proANF using an antibody to proANF, wherein an increase in proANF levels in the subject compared to normal indicates that the subject has sepsis, but not the full breadth of the claims meets

the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

3b. Claims 1-5, 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detection whether a subject has sepsis by assaying sera from said subject for pro-ANF using an antibody to pro-ANF, wherein an increase in pro-ANF levels in which the pro-ANF lacks a dipeptide, Xaa-Pro, at the amino-terminus in the subject compared to normal healthy sera indicates that the subject has sepsis, does not reasonably provide enablement for a method as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 1 is clearly a single means claim because it encompasses using all peptide prohormones to detect sepsis. Furthermore, the claim encompasses any "biological fluid" to be assayed. Claim 1 is a single means claim because the specification has only provided a description for a method of detecting sepsis, the method comprising assaying sera from a subject for levels of pro-ANF wherein high levels of pro-ANF relative to normal healthy sera indicates that the subject has sepsis. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712,714 - 715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). When claims depend on a recited property, a fact

situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a). Since no material limitations for "biological fluid" or "peptide prohormone" have been recited in the claims and only a desired activity has been recited, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. Therefore, not only proteins, such as pro-ANF, but also all other known and unknown prohormones, are encompassed by the scope of the claim. Similarly biological fluid ranges from blood, urine and lysates of cells separated from cell components. The claimed invention encompasses a method of detecting sepsis using compositions not envisioned or described in the specification, and neither does the specification disclose how these compositions can be distinguished from each other. The specification only enables a method of detecting sepsis in sera using a specific antibody to pro-ANF that lacks the dipeptide Xaa-Pro at the amino terminus. These properties of the prohormone differ structurally, chemically and physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which extracellular samples and affinity reagents are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the methods taught in the specification unpredictable (see pages 18-19). Therefore, it would require undue experimentation to determine which biological fluids and prohormones, would be encompassed by the scope of the method claims.

This disclosure is clearly insufficient support under the first paragraph of 35 U.S.C. 112 for claims, which encompass a method of detecting all "prohormones" using all "biological fluids". In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe detecting sepsis other than by assaying sera from the subject and using specific antibodies to pro-ANF, and since it is deemed to constitute undue experimentation to determine all

the others, the disclosure is not commensurate with the scope of the claims. It is suggested that by employing conventional claim language, the method claims be amended to include the specific limitations supported by the instant specification.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03).

Except for detecting in sera increased levels of pro-ANF, which lacks a di-peptide at the N-terminus (pages 18-19 and Figure 6), the instant specification does not adequately teach how to detect other prohormones as encompassed by claim 1.

The CAFC decision (Genentech Inc. v. Novo Nordisk, 42 USPQ2d 1001, 1997) expressly states that:

"When there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification,

not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Claim 1 is overly broad in its limitation of "at least one peptide prohormone". However, other than a method of detecting in sera for the increased levels of pro-ANF which lacks a di-peptide at the N-terminus (pages 18-19 and Figure 6), the instant specification does not adequately teach how to detect other prohormones as encompassed by claim 1. Thus, it would require undue experimentation on the part of the skilled artisan to use the claimed method as recited, in the absence of sufficient information to predict the results with an adequate degree of certainty. Given the breadth of claim 1 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of skill in the art to practice the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5, 7, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as vague and indefinite for several reasons.

Claim 1, line 3, is vague and indefinite because it recites "severe infections". The metes and bounds of this term are unclear. Does the term encompass *Staphylococcus aureus* infections as well as HIV infections?

Claim 1, line 6, is vague and indefinite because it recites "biological fluid". This limitation is unclear because it encompasses cell lysates, cell secretions as well as blood and urine and feces. It is suggested that this limitation be amended to recite "sera" in the claim to obviate this rejection.

Claim 1, line 4, is vague and indefinite because it recites "at least one peptide prohormone". The metes and bounds of this term are unclear. It is suggested that the elected prohormone be recited in the claim to obviate this rejection.

Claim 1, lines 4-5, is vague and indefinite because it recites "which is not the mature hormone obtainable from said peptide prohormone". It is suggested that the limitations from claims 3 and 4 be recited in claim 1 to obviate this rejection.

Claim 1, line 5, is vague and indefinite because it recites "derived therefrom". It is unclear how like the peptide prohormone the partial peptide is. It is suggested that the limitations from claims 3 and 4 be recited in claim 1 to obviate this rejection.

Claim 1, is vague and indefinite because it is incomplete. The claim fails to recite how the peptide prohormone is detected. The claim also fails to recite steps in the claimed method. The claim fails to recite a results step, i.e. what a decreased level or increased level of prohormone indicates. In addition, the claim fails to recite that there is a comparison to healthy normal sera.

Claim 1, line 1, is vague and indefinite because it recites "differential-diagnostic early detection". The metes and bounds of the term "early" are unclear.

Claim 2 is rejected as vague and indefinite because it recites non-elected subject matter.

Claim 3, line 4, is vague and indefinite because it is unclear which "peptide" is being referred to, the partial or the complete peptide.

Similarly, claim 7, line 4, is vague and indefinite because it is unclear which "peptide" is being referred to, the partial or the complete peptide

Claim 5, recites the limitation "said determination" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5, line 2, is vague and unclear because it recites that the "peptide prohormone" is detected in an "immunoassay or precipitation assay". It is unclear how the complete prohormone and the prohormone lacking the dipeptide at the amino terminal will be distinguished in the immunoassay.

Claim 4 is rejected as vague and indefinite insofar as it depends on the above rejected claims for its limitations.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 1-2, 5, are rejected under 35 U.S.C. 102(b) as being anticipated by Lubbesmeyer et al (1988).

The reference teaches detection of sepsis in sheep by an immunoassay of plasma in the sheep in which ANF is detected (see abstract; Figure 1, page R568). The

concentration of ANF was 13-fold higher within 2 hours after endotoxin administration (abstract, page R568, column 2, second para). Thus the reference anticipates instant claims 1-2, 5.

Conclusion

No claim is allowed.

Claims 1-5, 7 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
April 10, 2007